

Remarks

Applicants amended page 2, line 16 of the specification to correct a typographical error with respect to a patent number. The amendments of ranges for the amount of calcium salt in lines 4-5 on page 10 are supported by original claim 12. The “at least 40 wt. %” of bicarbonate in amended claims 1, 9 and 18 is supported at page 11, line 13 of the instant specification. The “and at least one water soluble carbonate salt” in amended claim 1 is supported by original claim 5 and page 11, lines 18-26 and page 12, lines 1-6 of the specification. Amended claims 6 and 13 now depend upon amended claim 1 since claim 5 has been cancelled. Amended claim 12 is supported by currently amended lines 4-5 on page 10. Applicants submit that no new matter has been added to the presently amended application. Applicants will advance arguments hereinbelow to illustrate the manner in which the presently claimed invention is patentably distinguishable from the cited and applied prior art. Reconsideration of the above-identified application is respectfully requested in view of the following remarks.

Rejection of Claims 1-6 and 8-20 under 35 U.S.C. §102(b) as being anticipated by Lee et al. (U.S. Pat. Nos. 6,248,310 or 6,214,321)

Examiner asserted that the amounts of each the calcium sulfate, the bicarbonate and the fluoride salt in the ‘310 patent anticipated the amounts of the elements in the present invention. However, in order to show anticipation under 35 U.S.C. §102(b), the reference must show every element of the claimed invention identically. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986), *Akzo N.V. v. United States Intl. Trade Commission*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986). The ‘310 patent cannot anticipate the present invention in view of presently amended claim 1. Presently amended claim 1 has at least 40 wt % of at least one bicarbonate salt and at least one water soluble carbonate salt in the second part.

Both ‘310 and ‘321 employ fluoride in the second part of its two part composition in amounts ranging from about 0.01 to about 5%, as in the present invention. Also, both patents disclose calcium salt and cite sulphates as an “illustrative calcium salt.” The ‘310 and ‘321 patents disclose use of monolithic compositions of water soluble calcium and phosphate salts, wherein “the term ‘monolithic’ is meant separate water soluble calcium

salts and phosphate salts which from solution may metathesize into calcium phosphates in solution or later upon mixing with the second composition.” See ‘310, col. 3, lns. 32-40 and ‘321, col. 3, lns. 16-24.

Both patents to Lee also disclose alkaline material but lists numerous examples of alkaline material such as potassium bicarbonate, potassium carbonate, calcium carbonate, calcium oxide, sodium hydroxide, potassium hydroxide and mixtures thereof. This list is in addition to the sodium bicarbonate and sodium carbonate used by the Applicants. Lee’s preferred ranges of alkaline material are “from 0.5 to 30%, more preferably from 1 to 20%, optimally from 3 to 15% by weight of the second composition” see ‘310 col. 3, lns. 55-65 and ‘321 col.3, lns. 39-49, and lists a broader range of “from 0.1 to 60%”. Notwithstanding the broad range of “from 0.1 to 60%” of alkaline material in Lee, the examples of the patents to Lee show that when a combination of alkali metal bicarbonate and alkali metal carbonate salts are used, levels of no more than 25% of bicarbonate salt are disclosed. See example 3 in each 6,248,310 and 6,214,321.

In contrast, the Applicants claim at least 40 wt. % of the bicarbonate salt present with carbonate salt. “In the presence of bicarbonate salts, the carbonate salt can ... be present in an amount sufficient to prevent the bicarbonate from reacting with the calcium to form carbon dioxide....” See. p. 12 lns. 5-10 of the application. Lee does not anticipate the combination of bicarbonate and carbonate salts where the level of bicarbonate is at least 40 wt. %.

The carbonate and bicarbonate salts disclosed in the Lee et al. patents are for the purposes of merely providing an alkaline material. No other purpose or advantage of these bicarbonate and carbonate salts is believed to be set forth. See p. 5 lines 14-17 of the application. The patents to Lee “require[] an alkaline material so that the second composition has a pH greater than 7, preferably from 7.2 to 11, more preferably from 8 to 10, optimally from 8.5 to 9.5. Alkaline materials suitable to achieve the pH are sodium bicarbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, calcium carbonate, calcium oxide, sodium hydroxide, potassium hydroxide and mixtures thereof” See ‘310 col. 3, lns. 55-62 and ‘321 col.3, lns. 39-45. Thus, in Lee, sodium bicarbonate and sodium carbonate are equivalent.

The present invention however does not use the carbonate and bicarbonate salts for a single purpose of buffering a solution as in Lee. The present application identifies different functions for the bicarbonate and carbonate salts. The carbonate salt serves “to help stabilize the composition by inhibiting reaction between the calcium salt and fluoride salt”, see p. 11 of the application, emphasis added. The bicarbonate is well known in the art of oral care “for providing good plaque removing capabilities … [and] a clean fresh feeling in the oral cavity after brushing and rinsing with water.” See application, p. 4, lns. 14-17. Though Lee discloses bicarbonate and carbonate salts, Lee fails to anticipate the present invention which uses a combination of bicarbonate salt at a specified level for providing good plaque removing capabilities and oral health and carbonate salts for inhibiting the reaction of calcium salt and fluoride salts. Lee does not anticipate such a combination.

In sum, the patents to Lee disclose the presently claimed elements; however, the mere presence of the claimed ingredients in Lee only supports the ideal that "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 U.S.P.Q. 865, 870 (Fed.Cir.1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 U.S.P.Q. 8, 12 (Fed.Cir.1983). The court also held that, “[a]n Examiner may often find every element of a claimed invention in the prior art. [However, if] identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue.” *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-1458 (Fed. Cir. 1998). Thus, despite the list of presently claimed elements disclosed in the patents to Lee, Lee fails to show the specific combination as presently claimed that being at least 40 wt. % sodium bicarbonate and a carbonate. As a result, Lee’s patents cannot anticipate the presently claimed invention.

New claims 21-30 are directed to a two part oral composition, the first part having at least one partially water soluble calcium salt, the second part having a fluoride salt, a bicarbonate salt, and a water soluble carbonate salt being present in a specific ratio to the calcium salt present in the composition. New claims 21-30 are not anticipated by the patents to Lee in light of the presence of carbonate and the claimed ratio of carbonate to calcium. With regard to the ratio, Examiner asserted the working example 3 at col. 7 of the ‘310 patent has the relative proportion of sodium carbonate to calcium salt falling

within the ratio recited in original claim 13. However, the working example 3 at col. 7 of the '310 patent does not teach the ratio of carbonate salt to calcium salt as recited in new claim 21. Applicants recognize the '310 and '321 patents disclose a combination of alkali metal bicarbonate salt and alkali metal carbonate salt which is used at levels of 0.4% by weight, see example 3 in each 6,248,310 and 6,214,321. The relative proportion of sodium carbonate to calcium salt, e.g. monocalcium phosphate, in '310 shows a 0.15:1 ratio, which is less than the newly claimed molar ratio of from about 0.2:1 to about 1:1 for a carbonate salt to calcium salt. The presently claimed ratio of carbonate salt to calcium salt is important "to aid in preventing the calcium/bicarbonate salt reaction...." See. p. 12 lns. 5-10 of the application. As a result, Lee fails to anticipate the presently claimed invention.

For the above-mentioned reasons, Applicants respectfully request that the present rejection be withdrawn for all the present claims on anticipation over Lee.

Rejection of Claims 1-6 and 8-20 under 35 U.S.C. §103 as being obvious over Lee et al. (U.S. Pat. Nos. 6,248,310 or 6,214,321), each primary reference being considered individually and separately and each being taken further in view of Gaffar et al (U.S. Pat. No. 4,177,258)

Examiner used Gaffar as a secondary reference to the patents of Lee to teach compositions which when mixed are neutral. All arguments made above under the anticipation rejection for Lee are reasserted here for the present obviousness rejection.

Gaffar discloses a dentifrice for dental remineralization with the optimum pH for remineralizing dentrifrices being between 5 and 9, particularly 6.8 and 7.5. Applicants realize oral compositions having a neutral pH are well-known in the art. However, in light of the previous anticipation arguments made in view of the patents to Lee, the Gaffar patent combined with both patents to Lee fails to render the present invention obvious. The patent to Gaffar fails to make up for the deficiencies of the patents to Lee relative to the combination of bicarbonate and carbonate salts claimed in each of the present independent claims. Consequently Gaffar cannot serve to make the presently claimed invention obvious. It is respectfully requested that the present rejection be withdrawn.

Rejection of Claim 7 under 35 U.S.C. §103 as being obvious over Lee et al. (U.S. Pat. Nos. 6,248,310 or 6,214,321), each primary reference being taken individually and separately and each further in view of Winston et al (U.S. Pat. No. 6,159,449)

Examiner used Winston as a secondary reference to the patents of Lee to teach the addition of water soluble orthophosphate salts to the fluoride-containing phase of a two-phase remineralizing dentifrice. Examiner recognized Winston did not disclose two phase compositions having the particular combination of components claimed instantly. Again, all anticipation rejection arguments made for Lee are reasserted here for the present obviousness rejection.

Applicants believe the arguments against Lee which are reasserted here obviate the present obviousness rejection using the Winston patent. Applicants are aware of the use of orthophosphate salts in Winston's '449 patent. Applicants understand the Winston patent discloses what was known by one of skill in the art. However, the mere presence of the orthophosphate salts in Winston's '449 patent cannot prove obviousness since "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 U.S.P.Q. 865, 870 (Fed.Cir.1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 U.S.P.Q. 8, 12 (Fed.Cir.1983).

In light of the previously anticipation arguments made in view of the patents to Lee, the Winston patent combined with both patents to Lee fails to render the present invention obvious. The patent to Winston fails to make up for the deficiencies of the patents to Lee relative to the combination of bicarbonate and carbonate salts claimed in each of the present independent claims. Consequently Winston cannot serve to make the presently claimed invention obvious. It is respectfully requested that the present rejection be withdrawn.

Rejection of Claim 7 under 35 U.S.C. §103 as being obvious over Lee et al.
(U.S. Pat. Nos. 6,248,310 or 6,214,321), each primary reference being taken individually
and separately and each further in view of Winston et al (U.S. Pat. No. 6,159,449) and
each combination of primary references being taken further in view of Gaffar et al (U.S.
Pat. No. 4,177,258)

The arguments asserted above against both patents to Lee, Winston and Gaffar are reasserted here. The combination of Winston and Gaffar still fail to make up for the deficiencies of both patents to Lee again with respect to the specific combination of bicarbonate and carbonate salts claimed. Accordingly, the cited prior art fails to render the present invention obvious.

Applicant respectfully submits that the application is in condition for allowance. If such is not the case, the Examiner is requested to kindly contact the undersigned in an effort to satisfactorily conclude the prosecution of this application.

Respectfully submitted,

2/27/2006
Date



Stuart D. Frenkel
Reg. No. 29,500

Frenkel & Associates
3975 University Drive, Suite 330
Fairfax, VA 22030
Telephone (703) 246-9641
Facsimile (703) 246-9646